IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

MERCK SHARP & DOHME CORP.,

Plaintiff,

v.

MYLAN PHARMACEUTICALS INC., and MYLAN INC.,

Defendants.

C.A. No. 1:19CV101
Keeley

COMPLAINT

Plaintiff Merck Sharp & Dohme Corp. ("Merck"), by its attorneys, for its Complaint, alleges as follows:

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, and for a declaratory judgment of patent infringement under 28 U.S.C. §§ 2201 and 2202 and the patent laws of the United States, Title 35, United States Code, that arises out of defendants' submission of Abbreviated New Drug Application ("ANDA") Nos. 202473 and 202478 to the U.S. Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, sell, and/or import versions of JANUVIA® (sitagliptin phosphate) and JANUMET® (metformin hydrochloride; sitagliptin phosphate) prior to the expiration of U.S. Patent No. 7,326,708 ("the '708 patent") and U.S. Patent No. 8,414,921 ("the '921 patent").

2. Mylan Pharmaceuticals Inc. notified Merck by letter dated December 28, 2010 ("Mylan's '473 Notice Letter") that it had submitted to the FDA ANDA No. 202473 ("Mylan's '473 ANDA"), seeking approval from the FDA to engage in the commercial manufacture, use,

offering for sale, sale, and/or importation of generic sitagliptin phosphate oral tablets ("Mylan's '473 ANDA Product") prior to the expiration of the '708 patent.

3. On information and belief, Mylan's '473 ANDA Product is a generic version of Merck's JANUVIA® product.

4. Mylan Pharmaceuticals Inc. notified Merck by letter dated December 28, 2010 ("Mylan's First '478 Notice Letter") that it had submitted to the FDA ANDA No. 202478 ("Mylan's '478 ANDA"), seeking approval from the FDA to engage in the commercial manufacture, use, offering for sale, sale, and/or importation of generic metformin hydrochloride and sitagliptin phosphate oral tablets ("Mylan's '478 ANDA Product") prior to the expiration of the '708 patent.

5. Mylan Pharmaceuticals Inc. notified Merck by letter dated September 13, 2013 ("Mylan's Second '478 Notice Letter") that it had amended Mylan's '478 ANDA to additionally seek approval from the FDA to engage in the commercial manufacture, use, offering for sale, sale, and/or importation of Mylan's '478 ANDA Product prior to the expiration of the '921 patent.

6. On information and belief, Mylan's '478 ANDA Product is a generic version of Merck's JANUMET® product

7. Mylan's '473 Notice Letter, Mylan's First '478 Notice Letter, and Mylan's Second '478 Notice Letter are collectively referred to herein as "Mylan's Notice Letters." Mylan's '473 ANDA and Mylan's '478 ANDA are collectively referred to herein as "Mylan's ANDAs." Mylan's '473 ANDA Product and Mylan's '478 ANDA Product are collectively referred to herein as "Mylan's ANDA Products."

PARTIES

8. Plaintiff Merck is a corporation organized and existing under the laws of New Jersey, having its corporate offices and principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889.

9. Merck is the holder of New Drug Application ("NDA") No. 21995 for JANUVIA® (sitagliptin phosphate), which has been approved by the FDA.

10. Merck is the holder of NDA No. 22044 for JANUMET® (metformin hydrochloride; sitagliptin phosphate), which has been approved by the FDA.

11. On information and belief, defendant Mylan Pharmaceuticals Inc. ("MPI") is a corporation organized and existing under the laws of the State of West Virginia, having its principal place of business at 781 Chestnut Ridge Road, Morgantown, WV 26505. On information and belief, MPI is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs for the U.S. market.

12. On information and belief, defendant Mylan Inc. is a corporation organized and existing under the laws of the State of Pennsylvania, having its principal place of business at 1000 Mylan Boulevard, Canonsburg, PA 15317. On information and belief, Mylan Inc. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs through various operating subsidiaries, including MPI.

13. On information and belief, MPI is a wholly owned subsidiary of Mylan Inc. MPI and Mylan Inc. are collectively referred to herein as "Mylan."

14. On information and belief, MPI and Mylan Inc. acted in concert to prepare and submit Mylan's ANDAs to the FDA.

15. On information and belief, MPI and Mylan Inc. know and intend that upon approval of Mylan's ANDAs, MPI and Mylan Inc. will manufacture, market, sell, and distribute

Mylan's ANDA Products throughout the United States, including in West Virginia. On information and belief, MPI and Mylan Inc. are agents of each other and/or operate in concert as integrated parts of the same business group, including with respect to Mylan's ANDA Products, and enter into agreements that are nearer than arm's length. On information and belief, MPI and Mylan Inc. participated, assisted, and cooperated in carrying out the acts complained of herein.

16. On information and belief, following any FDA approval of Mylan's ANDAs, MPI and Mylan will act in concert to distribute and sell Mylan's ANDA Products throughout the United States, including within West Virginia.

JURISDICTION

17. This Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

18. This Court has personal jurisdiction over Mylan.

19. MPI is subject to personal jurisdiction in West Virginia because, among other things, it has purposely availed itself of the benefits and protections of West Virginia's laws such that it should reasonably anticipate being haled into court here. In addition, on information and belief, MPI develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of , and therefore transacts business within the State of West Virginia related to Merck's claims, and/or has engaged in systematic and continuous business contacts within the State of West Virginia

20. Mylan Inc. is subject to personal jurisdiction in West Virginia because, among other things, Mylan Inc., itself and through its wholly owned subsidiary MPI, has purposefully availed itself of the benefits and protections of West Virginia's laws such that it should reasonably anticipate being haled into court here. On information and belief, Mylan Inc., itself and through its wholly owned subsidiary MPI, develops, manufactures, imports, markets, offers

to sell, and/or sells generic drugs throughout the United States, including in the State of West Virginia, and therefore transacts business within the State of West Virginia, and/or has engaged in systematic and continuous business contacts within the State of West Virginia. In addition, Mylan Inc. is subject to personal jurisdiction in West Virginia because, on information and belief, it controls and dominates MPI, and therefore the activities of MPI in this jurisdiction are attributed to Mylan Inc.

21. On information and belief, if Mylan's ANDAs are approved, Mylan will manufacture, market, sell; and/or distribute Mylan's ANDA Products within the United States, including in West Virginia, consistent with Mylan's practices for the marketing and distribution of other generic pharmaceutical products. On information and belief, Mylan regularly does business in West Virginia, and its practices with other generic pharmaceutical products have involved placing those products into the stream of commerce for distribution throughout the United States, including in West Virginia. On information and belief, Mylan's generic pharmaceutical products are used and/or consumed within and throughout the United States, including in West Virginia. On information and belief, Mylan's ANDA Products will be prescribed by physicians practicing in West Virginia, dispensed by pharmacies located within West Virginia, and used by patients in West Virginia. Each of these activities would have a substantial effect within West Virginia and would constitute infringement of Merck's patent in the event that Mylan's ANDA Products are approved before the patent expires. Each of these activities would have a substantial effect within West Virginia and would constitute infringement of Merck's patent rights in the even that Mylan's ANDA Product is approved before

22. On information and belief, Mylan derives substantial revenue from generic pharmaceutical products that are used and/or consumed within West Virginia, and that are

manufactured by Mylan and/or for which MPI and/or Mylan Inc. is/are the named applicant(s) on approved ANDAs. On information and belief, various products for which MPI and/or Mylan Inc. is/are the named applicant(s) on approved ANDAs are available at retail pharmacies in West Virginia.

VENUE

23. Merck incorporates each of the preceding paragraphs 1–22 as if fully set forth herein.

24. Venue is proper in this district as to MPI under 28 U.S.C. § 1400(b) because MPI is a corporation organized and existing under the laws of the State of West Virginia and is subject to personal jurisdiction in this judicial district.

25. Venue is proper in this district as to Mylan Inc. under 28 U.S.C. § 1400(b) because Mylan Inc. is subject to personal jurisdiction in this judicial district, has previously consented to venue in this judicial district, and on information and belief will consent to venue for the purpose of this case.

THE '708 PATENT

26. Merck incorporates each of the preceding paragraphs 1–25 as if fully set forth herein.

27. The inventors named on the '708 patent are Stephen Howard Cypes, Alex Minhua Chen, Russell R. Ferlita, Karl Hansen, Ivan Lee, Vicky K. Vydra, and Robert M. Wenslow, Jr.

28. The '708 patent, entitled "Phosphoric Acid Salt of a Dipeptidyl Peptidase-IV Inhibitor" (attached as Exhibit A), was duly and legally issued on February 5, 2008.

29. Merck is the owner and assignee of the '708 patent.

30. The '708 patent claims, *inter alia*, a dihydrogenphosphate salt of 4-oxo-4-[3-(trifluoromethyl)-5,6-dihydro[1,2,4]triazolo[4,3-a]pyrazin-7(8H)-yl]-1-(2,4,5-

trifluorophenyl)butan-2-amine of structural formula I, or a hydrate thereof, as recited in claim 1 of the '708 patent.

31. JANUVIA®, as well as methods of using JANUVIA®, are covered by one or more claims of the '708 patent, including claim 1 of the '708 patent, and the '708 patent has been listed in connection with JANUVIA® in the FDA's Orange Book.

32. JANUMET®, as well as methods of using JANUMET®, are covered by one or more claims of the '708 patent, including claim 1 of the '708 patent, and the '708 patent has been listed in connection with JANUMET® in the FDA's Orange Book.

THE '921 PATENT

33. Merck incorporates each of the preceding paragraphs 1–32 as if fully set forth herein.

34. The inventors named on the '921 patent are Ashkan Kamali, Laman Alani, Kyle A. Fliszar, Soumojeet Ghosh, and Monica Tijerina.

35. The '921 patent, entitled "Pharmaceutical Compositions of Combinations of Dipeptidyl Peptidase-4 Inhibitors with Metformin" (attached as Exhibit B), was duly and legally issued on April 9, 2013.

36. Merck is the owner and assignee of the '921 patent.

37. The '921 patent claims, *inter alia*, a pharmaceutical composition comprising: (a) about 3 to 20% by weight of sitagliptin, or a pharmaceutically acceptable salt thereof; (b) about 25 to 94% by weight of metformin hydrochloride; (c) about 0.1 to 10% by weight of a lubricant; (d) about 0 to 35% by weight of a binding agent; (e) about 0.5 to 1% by weight of a surfactant; and (f) about 5 to 15% by weight of a diluent, as recited in claim 1 of the '921 patent.

38. JANUMET®, as well as methods of using JANUMET®, are covered by one or more claims of the '921 patent, including claim 1 of the '921 patent, and the '921 patent has been listed in connection with JANUMET® in the FDA's Orange Book.

COUNT I – INFRINGEMENT OF THE '708 PATENT
(MYLAN'S '473 ANDA PRODUCT)

39. Merck incorporates each of the preceding paragraphs 1–38 as if fully set forth herein.

40. In Mylan's '473 Notice Letter, Mylan notified Merck of the submission of Mylan's '473 ANDA to the FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Mylan's '473 ANDA Product prior to the expiration of the '708 patent.

41. In Mylan's '473 Notice Letter, Mylan also notified Merck that, as part of its ANDA, Mylan had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355 (j)(2)(A)(vii)(IV), with respect to the '708 patent. On information and belief, Mylan submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '708 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Mylan's '473 ANDA Product.

42. In Mylan's '473 Notice Letter, Mylan stated that Mylan's '473 ANDA Product contains sitagliptin phosphate as an active ingredient.

43. Mylan's '473 ANDA Product, and the use of Mylan's '473 ANDA Product, are covered by one or more claims of the '708 patent, including at least claim 1 of the '708 patent, because claim 1 of the '708 patent covers the sitagliptin phosphate contained in Mylan's '473 ANDA Product.

44. In Mylan's '473 Notice Letter, Mylan did not contest infringement of claim 1 of the '708 patent.

45. Mylan's submission of Mylan's '473 ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's '473 ANDA Product before the expiration of the '708 patent was an act of infringement of the '708 patent under 35 U.S.C. § 271(e)(2)(A).

46. On information and belief, Mylan will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's '473 ANDA Product immediately and imminently upon approval of its ANDA.

47. The manufacture, use, sale, offer for sale, or importation of Mylan's '473 ANDA Product would infringe one or more claims of each of the '708 patent, including at least claim 1 of the '708 patent.

48. On information and belief, the manufacture, use, sale, offer for sale, or importation of Mylan's '473 ANDA Product in accordance with, and as directed by, its proposed product labeling would infringe one or more claims of the '708 patent, including at least claim 1 of the '708 patent.

49. On information and belief, Mylan plans and intends to, and will, actively induce infringement of the '708 patent when Mylan's '473 ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Mylan's activities will be done with knowledge of the '708 patent and specific intent to infringe that patent.

50. On information and belief, Mylan knows that Mylan's '473 ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '708 patent, that Mylan's '473 ANDA Product is not a staple article or commodity of commerce, and that

Mylan's '473 ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, Mylan plans and intends to, and will, contribute to infringement of the '708 patent immediately and imminently upon approval of Mylan's '473 ANDA.

51. Notwithstanding Mylan's knowledge of the claims of the '708 patent, Mylan has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Mylan's '473 ANDA Product with its product labeling following FDA approval of Mylan's '473 ANDA prior to the expiration of the '708 patent.

52. The foregoing actions by Mylan constitute and/or will constitute infringement of the '708 patent; active inducement of infringement of the '708 patent; and contribution to the infringement by others of the '708 patent.

53. On information and belief, Mylan has acted with full knowledge of the '708 patent and without a reasonable basis for believing that it would not be liable for infringement of the '708 patent; active inducement of infringement of the '708 patent; and/or contribution to the infringement by others of the '708 patent.

54. Merck will be substantially and irreparably damaged by infringement of the '708 patent.

55. Unless Mylan is enjoined from infringing the '708 patent, actively inducing infringement of the '708 patent, and contributing to the infringement by others of the '708 patent, Merck will suffer irreparable injury. Merck has no adequate remedy at law.

COUNT II – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '708 PATENT (MYLAN'S '473 ANDA PRODUCT)

56. Merck incorporates each of the preceding paragraphs 1–55 as if fully set forth herein.

57. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Merck on the one hand and Mylan on the other regarding Mylan's infringement, active inducement of infringement, and contribution to the infringement by others of the '708 patent.

58. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Mylan's '473 ANDA Product with its proposed labeling, or any other Mylan drug product that is covered by or whose use is covered by the '708 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the '708 patent, and that the claims of the '708 patent are valid.

COUNT III – INFRINGEMENT OF THE '708 PATENT
(MYLAN'S '478 ANDA PRODUCT)

59. Merck incorporates each of the preceding paragraphs 1–58 as if fully set forth herein.

60. In Mylan's First '478 Notice Letter, Mylan notified Merck of the submission of Mylan's '478 ANDA to the FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Mylan's '478 ANDA Product prior to the expiration of the '708 patent.

61. In Mylan's First '478 Notice Letter, Mylan also notified Merck that, as part of its ANDA, Mylan had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355 (j)(2)(A)(vii)(IV), with respect to the '708 patent. On information and belief, Mylan submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '708 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Mylan's '478 ANDA Product.

62. In Mylan's First '478 Notice Letter, Mylan stated that Mylan's '478 ANDA Product contains sitagliptin phosphate as an active ingredient.

63. Mylan's '478 ANDA Product, and the use of Mylan's '478 ANDA Product, are covered by one or more claims of the '708 patent, including at least claim 1 of the '708 patent, because claim 1 of the '708 patent covers the sitagliptin phosphate contained in Mylan's '478 ANDA Product.

64. In Mylan's First '478 Notice Letter, Mylan did not contest infringement of claim 1 of the '708 patent.

65. Mylan's submission of Mylan's '478 ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's '478 ANDA Product before the expiration of the '708 patent was an act of infringement of the '708 patent under 35 U.S.C. § 271(e)(2)(A).

66. On information and belief, Mylan will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's '478 ANDA Product immediately and imminently upon approval of its ANDA.

67. The manufacture, use, sale, offer for sale, or importation of Mylan's '478 ANDA Product would infringe one or more claims of the '708 patent, including at least claim 1 of the '708 patent.

68. On information and belief, the manufacture, use, sale, offer for sale, or importation of Mylan's '478 ANDA Product in accordance with, and as directed by, its proposed product labeling would infringe one or more claims of the '708 patent, including at least claim 1 of the '708 patent.

69. On information and belief, Mylan plans and intends to, and will, actively induce infringement of the '708 patent when Mylan's '478 ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Mylan's activities will be done with knowledge of the '708 patent and specific intent to infringe that patent.

70. On information and belief, Mylan knows that Mylan's '478 ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '708 patent, that Mylan's '478 ANDA Product is not a staple article or commodity of commerce, and that Mylan's '478 ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, Mylan plans and intends to, and will, contribute to infringement of the '708 patent immediately and imminently upon approval of Mylan's '478 ANDA.

71. Notwithstanding Mylan's knowledge of the claims of the '708 patent, Mylan has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Mylan's '478 ANDA Product with its product labeling following FDA approval of Mylan's '478 ANDA prior to the expiration of the '708 patent.

72. The foregoing actions by Mylan constitute and/or will constitute infringement of the '708 patent; active inducement of infringement of the '708 patent; and contribution to the infringement by others of the '708 patent.

73. On information and belief, Mylan has acted with full knowledge of the '708 patent and without a reasonable basis for believing that it would not be liable for infringement of the '708 patent; active inducement of infringement of the '708 patent; and/or contribution to the infringement by others of the '708 patent.

74. Merck will be substantially and irreparably damaged by infringement of the '708 patent.

75. Unless Mylan is enjoined from infringing the '708 patent, actively inducing infringement of the '708 patent, and contributing to the infringement by others of the '708 patent, Merck will suffer irreparable injury. Merck has no adequate remedy at law.

COUNT IV – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '708 PATENT (MYLAN'S '478 ANDA PRODUCT)

76. Merck incorporates each of the preceding paragraphs 1–75 as if fully set forth herein.

77. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Merck on the one hand and Mylan on the other regarding Mylan's infringement, active inducement of infringement, and contribution to the infringement by others of the '708 patent.

78. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Mylan's '478 ANDA Product with its proposed labeling, or any other Mylan drug product that is covered by or whose use is covered by the '708 patent, will infringe, induce the infringement of and contribute to the infringement by others of, the '708 patent, and that the claims of the '708 patent are valid.

COUNT V – INFRINGEMENT OF THE '921 PATENT (MYLAN'S '478 ANDA PRODUCT)

79. Merck incorporates each of the preceding paragraphs 1–78 as if fully set forth herein.

80. In Mylan's Second '478 Notice Letter, Mylan notified Merck of the submission of Mylan's '478 ANDA to the FDA. The purpose of this submission was to obtain approval under

the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Mylan's '478 ANDA Product prior to the expiration of the '921 patent.

81. In Mylan's Second '478 Notice Letter, Mylan also notified Merck that, as part of its ANDA, Mylan had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355 (j)(2)(A)(vii)(IV), with respect to the '921 patent. On information and belief, Mylan submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '921 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Mylan's '478 ANDA Product.

82. Mylan's '478 ANDA Product, and the use of Mylan's '478 ANDA Product, are covered by one or more claims of the '921 patent, including at least claim 1 of the '921 patent, because the composition of Mylan's '478 ANDA Product includes the same or equivalent ingredients as recited in claim 1 of the '921 patent in the same or equivalent amounts.

83. Mylan's submission of Mylan's '478 ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's '478 ANDA Product before the expiration of the '921 patent was an act of infringement of the '921 patent under 35 U.S.C. § 271(e)(2)(A).

84. On information and belief, Mylan will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's '478 ANDA Product immediately and imminently upon approval of its ANDA.

85. The manufacture, use, sale, offer for sale, or importation of Mylan's '478 ANDA Product would infringe one or more claims of the '921 patent, including at least claim 1 of the '921 patent.

86. On information and belief, the manufacture, use, sale, offer for sale, or importation of Mylan's '478 ANDA Product in accordance with, and as directed by, its proposed product labeling would infringe one or more claims of the '921 patent, including at least claim 1 of the '921 patent.

87. On information and belief, Mylan plans and intends to, and will, actively induce infringement of the '921 patent when Mylan's '478 ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Mylan's activities will be done with knowledge of the '921 patent and specific intent to infringe that patent.

88. On information and belief, Mylan knows that Mylan's '478 ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '921 patent, that Mylan's '478 ANDA Product is not a staple article or commodity of commerce, and that Mylan's '478 ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, Mylan plans and intends to, and will, contribute to infringement of the '921 patent immediately and imminently upon approval of Mylan's '478 ANDA.

89. Notwithstanding Mylan's knowledge of the claims of the '921 patent, Mylan has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Mylan's '478 ANDA Product with its product labeling following FDA approval of Mylan's '478 ANDA prior to the expiration of the '921 patent.

90. The foregoing actions by Mylan constitute and/or will constitute infringement of the '921 patent; active inducement of infringement of the '921 patent; and contribution to the infringement by others of the '921 patent.

91. On information and belief, Mylan has acted with full knowledge of the '921 patent and without a reasonable basis for believing that it would not be liable for infringement of the '921 patent; active inducement of infringement of the '921 patent; and/or contribution to the infringement by others of the '921 patent.

92. Merck will be substantially and irreparably damaged by infringement of the '921 patent.

93. Unless Mylan is enjoined from infringing the '921 patent, actively inducing infringement of the '921 patent, and contributing to the infringement by others of the '921 patent, Merck will suffer irreparable injury. Merck has no adequate remedy at law.

COUNT VI – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '921 PATENT (MYLAN'S '478 ANDA PRODUCT)

94. Merck incorporates each of the preceding paragraphs 1–93 as if fully set forth herein.

95. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Merck on the one hand and Mylan on the other regarding Mylan's infringement, active inducement of infringement, and contribution to the infringement by others of the '921 patent.

96. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Mylan's '478 ANDA Product with its proposed labeling, or any other Mylan drug product that is covered by or whose use is covered by the '921 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the '921 patent, and that the claims of the '921 patent are valid.

PRAYER FOR RELIEF

WHEREFORE, Merck requests the following relief:

(a) A judgment that the '708 patent has been infringed under 35 U.S.C. § 271(e)(2) by Mylan's submissions to the FDA of Mylan's ANDAs;

(b) A judgment ordering that the effective date of any FDA approval of the commercial manufacture, use, or sale of Mylan's ANDA Products, or any other drug product that infringes or the use of which infringes the '708 patent, be not earlier than the latest of the expiration date of the '708 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction enjoining Mylan, and all persons acting in concert with Mylan, from the commercial manufacture, use, sale, offer for sale, or importation into the United States of Mylan's ANDA Products, or any other drug product covered by or whose use is covered by the '708 patent, prior to the expiration of the '708 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A judgment declaring that the commercial manufacture, use, sale, offer for sale or importation of Mylan's ANDA Products, or any other drug product that is covered by or whose use is covered by the '708 patent, prior to the expiration of the '708 patent, will infringe, induce the infringement of, and contribute to the infringement by others of, the '708 patent;

(e) A judgment that the '921 patent has been infringed under 35 U.S.C. § 271(e)(2) by Mylan's submission to the FDA of Mylan's '478 ANDA;

(f) A judgment ordering that the effective date of any FDA approval of commercial manufacture, use, or sale of Mylan's '478 ANDA Product, or any other drug product that infringes or the use of which infringes the '921 patent, be not earlier than the latest of the expiration date of the '921 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(g) A preliminary and permanent injunction enjoining Mylan, and all persons acting in concert with Mylan, from the commercial manufacture, use, sale, offer for sale, or importation into the United States of Mylan's '478 ANDA Product, or any other drug product covered by or whose use is covered by the '921 patent, prior to the expiration of the '921 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(h) A judgment declaring that the commercial manufacture, use, sale, offer for sale or importation of Mylan's '478 ANDA Product, or any other drug product that is covered by or whose use is covered by the '921 patent, prior to the expiration of the '921 patent, will infringe, induce the infringement of, and contribute to the infringement by others of, the '921 patent;

(i) A declaration that this is an exceptional case and an award of attorney's fees pursuant to 35 U.S.C. § 285;

(j) Costs and expenses in this action; and

(k) Such further and other relief as this Court may deem just and proper.

Dated: May 2, 2019

Respectfully submitted,

SCHRADER COMPANION DUFF & LAW, PLLC

/s/ James F. Companion
James F. Companion
401 Main Street
Wheeling, WV 26003
(304) 233-3390
jfc@schraderlaw.com

Attorneys for Plaintiff
Merck Sharp & Dohme Corp.

OF COUNSEL:

Bruce R. Genderson
Jessamyn S. Berniker
Stanley E. Fisher
Alexander S. Zolan
Shaun P. Mahaffy
Anthony H. Sheh
Jingyuan Luo*
WILLIAMS & CONNOLLY LLP
725 Twelfth Street, N.W.
Washington, DC 20005
T: (202) 434-5000
F: (202) 434-5029
bgenderson@wc.com
jberniker@wc.com
sfisher@wc.com

smahaffy@wc.com
asheh@wc.com
jluo@wc.com

**Admitted only in California. Practice supervised by D.C. Bar members pursuant to D.C. Court of Appeals Rule 49(c)(8).*